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EXAMINER	
ROARK, JESSICA H	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/728,420	Applicant(s) YOSHINAGA ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Sequence Compliance

1. Sequence compliance: The CRF, paper copy of the Sequence Listing and Statement that the CRF and Sequence Listing are identical, filed 7/2/01, has been found acceptable and entered.

However,
2. The specification is objected to under 37 CFR 1.821(d) because the SEQ ID NOS are not disclosed in the specification adjacent referenced sequences (for example, sequences appear in the Figures, but lack identifiers in the Figures or Brief Description of the Figures). *Appropriate correction is required.* Applicant is reminded that if any sequence described in either the body of the specification or figures is not represented in the sequence listing, a substitute sequence listing, paper copy and CRF is required.

Restriction Requirement

3. The following is noted:

A) There is some confusion as to the identity of the various sequences when the various sections of the specification is considered. In particular, it is unclear from the reference to various Figures in the claims that the appropriate sequence identifier is provided. For example, is Figure 3A/SEQ ID NO:6 of mouse or human origin? The sequence listing indicates that SEQ ID NO:6 is mouse, whereas Figure 3A describes a human sequence (see page 11 of the specification).

Applicant is required to carefully review the specification and claims for correspondence of sequence identifiers to the appropriate sequences. It is further suggested that the reference to Figures be removed from the claims and only sequence identifiers used. The restriction has been set forth for each SEQ ID NO:, as noted below in the listing of the Groups.

B) The dependency of several claims appears to be incorrect (e.g., claim 5 refers to the host cell of claim 3, but claim 3 is a nucleic acid; claim 14 refers to the antibody of claim 11, but claim 11 is a polypeptide). The restriction has been set forth based upon textual dependency in view of these inconsistencies. Applicant should carefully review the dependency of the instant claims and make the appropriate corrections.

C) The specification discloses several polypeptides, each of which has *a distinct structure* as shown by the unique sequence identifiers, even though the same term may be used to encompass more than one polypeptide (e.g., "B7RP1"). A search for any one of these sequences is not co-extensive with a search for any of the others. Further, because each of these polypeptides is structurally distinct (including the three polypeptides encompassed by the term "B7RP1"); the polynucleotides encoding these polypeptides, the antibodies which bind each polypeptides and transgenic mammals expressing these polypeptides are also distinct. These structurally distinct products are subject to restriction, rather than election of species, because they do not share *a substantial structural feature essential to a common utility* (as per MPEP 803.02) *Therefore, the restriction has been set forth for each product as a separate group, irrespective of the format of the claims.*

D) Method claims 24, 25, 26, 28, 30, 32, 33, 39 and 42 each employ multiple structurally distinct products, as noted supra in C, that do not share *a substantial structural feature essential to a common utility*. Consequently, within a given claim multiple methods are recited which differ at least with respect to the method steps because different products are utilized. *Therefore, the restriction has been set forth for each as a separate group, irrespective of the format of the claims*

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 and 3-7, drawn to an isolated nucleotide sequence related to SEQ ID NO:1, vectors, host cells, and methods of producing the polypeptide; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

II. Claims 2-7, drawn to an isolated nucleotide sequence related to SEQ ID NO:11, vectors, host cells, and methods of producing the polypeptide; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

III. Claims 2-7, drawn to an isolated nucleotide sequence related to SEQ ID NO:6, vectors, host cells, and methods of producing the polypeptide; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

IV. Claims 2-7, drawn to an isolated nucleotide sequence related to SEQ ID NO:16, vectors, host cells, and methods of producing the polypeptide; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

V. Claims 8-9, 11 and 19-23, drawn to a polypeptide related to SEQ ID NO:2 encoded by SEQ ID NO:1, fragments and compositions thereof, and heterologous proteins comprising said polypeptide; classified in Class 530, subclasses 395, 837, and 866 and Class 424, subclass 184.1.

VI. Claims 8, 10, 12 and 19-23, drawn to a polypeptide related to SEQ ID NO:7 encoded by SEQ ID NO:1, fragments and compositions thereof, and heterologous proteins comprising said polypeptide; classified in Class 530, subclasses 395, 837, and 866 and Class 424, subclass 184.1.

VII. Claims 8, 10, 12 and 19-23, drawn to a polypeptide related to SEQ ID NO:12 encoded by SEQ ID NO:1, fragments and compositions thereof, and heterologous proteins comprising said polypeptide; classified in Class 530, subclasses 395, 837, and 866 and Class 424, subclass 184.1.

VIII. Claims 8, 10, 12 and 19-23, drawn to a polypeptide related to SEQ ID NO:17 encoded by SEQ ID NO:1, fragments and compositions thereof, and heterologous proteins comprising said polypeptide; classified in Class 530, subclasses 395, 837, and 866 and Class 424, subclass 184.1.

IX. Claims 13-16 and 18, drawn to an antibody or fragment thereof which binds a polypeptide related to SEQ ID NO:2; classified in Class 530, subclass 387.3.

X. Claims 13-18, drawn to an antibody or fragment thereof which binds a polypeptide related to SEQ ID NO:7; classified in Class 530, subclass 387.3.

XI. Claims 13-18, drawn to an antibody or fragment thereof which binds a polypeptide related to SEQ ID NO:12; classified in Class 530, subclass 387.3.

XII. Claims 13-18, drawn to an antibody or fragment thereof which binds a polypeptide related to SEQ ID NO:17; classified in Class 530, subclass 387.3.

XIII. Claim 24, drawn to a method of treating or preventing a T cell mediated disorder by administering a polypeptide related to SEQ ID NO:2, classified in Class 514, subclass 885.

XIV. Claim 24, drawn to a method of treating or preventing a T cell mediated disorder by administering a polypeptide related to SEQ ID NO:7, classified in Class 514, subclass 885.

XV. Claim 24, drawn to a method of treating or preventing a T cell mediated disorder by administering a polypeptide related to SEQ ID NO:12, classified in Class 514, subclass 885.

XVI. Claim 24, drawn to a method of treating or preventing a T cell mediated disorder by administering a polypeptide related to SEQ ID NO:17, classified in Class 514, subclass 885.

XVII. Claim 25, drawn to a method of diagnosing a T cell mediated disorder by detecting a polypeptide related to SEQ ID NO:2, classified in Class 435, subclass 7.1.

XVIII. Claim 25, drawn to a method of diagnosing a T cell mediated disorder by detecting a polypeptide related to SEQ ID NO:7, classified in Class 435, subclass 7.1.

XIX. Claim 25, drawn to a method of diagnosing a T cell mediated disorder by detecting a polypeptide related to SEQ ID NO:12, classified in Class 435, subclass 7.1.

XX. Claim 25, drawn to a method of diagnosing a T cell mediated disorder by detecting a polypeptide related to SEQ ID NO:17, classified in Class 435, subclass 7.1.

XXI. Claims 26-27, drawn to a method of identifying a test molecule which binds to a polypeptide related to SEQ ID NO:2, classified in Class 435, subclass 7.8.

XXII. Claims 26-27, drawn to a method of identifying a test molecule which binds to a polypeptide related to SEQ ID NO:7, classified in Class 435, subclass 7.8.

XXIII. Claims 26-27, drawn to a method of identifying a test molecule which binds to a polypeptide related to SEQ ID NO:12, classified in Class 435, subclass 7.8.

XXIV. Claims 26-27, drawn to a method of identifying a test molecule which binds to a polypeptide related to SEQ ID NO:17, classified in Class 435, subclass 7.8.

XXV. Claim 28, drawn to a method of regulating T cell activation by administering a nucleic acid related to SEQ ID NO:1, classified in Class 514, subclass 44.

XXVI. Claim 28, drawn to a method of regulating T cell activation by administering a nucleic acid related to SEQ ID NO:6, classified in Class 514, subclass 44.

XXVII. Claim 28, drawn to a method of regulating T cell activation by administering a nucleic acid related to SEQ ID NO:11, classified in Class 514, subclass 44.

XXVIII. Claim 28, drawn to a method of regulating T cell activation by administering a nucleic acid related to SEQ ID NO:16, classified in Class 514, subclass 44.

XXIX. Claim 29, drawn to a transgenic non-human mammal comprising a nucleic acid molecule related to SEQ ID NO:1, classified in Class 800, subclass 13.

XXX. Claim 29, drawn to a transgenic non-human mammal comprising a nucleic acid molecule related to SEQ ID NO:6, classified in Class 800, subclass 13.

XXXI. Claim 29, drawn to a transgenic non-human mammal comprising a nucleic acid molecule related to SEQ ID NO:11, classified in Class 800, subclass 13.

XXXII. Claim 29, drawn to a transgenic non-human mammal comprising a nucleic acid molecule related to SEQ ID NO:16, classified in Class 800, subclass 13.

XXXIII. Claims 30, 32-33 and 35-36, drawn to a method of suppressing an immune response/IgE production by administering an antagonist of the CRP1 polypeptide of SEQ ID NO:2, classified in Class 424, subclass 143.1.

XXXIV. Claims 30-34 and 36, drawn to a method of suppressing an immune response/IgE production by administering an antagonist of the B7RP1 polypeptide of SEQ ID NO:7, classified in Class 424, subclass 143.1.

XXXV. Claims 30-34 and 36, drawn to a method of suppressing an immune response/IgE production by administering an antagonist of the B7RP1 polypeptide of SEQ ID NO:12, classified in Class 424, subclass 143.1.

XXXVI. Claims 30-34 and 36, drawn to a method of suppressing an immune response/IgE production by administering an antagonist of the B7RP1 polypeptide of SEQ ID NO:17, classified in Class 424, subclass 143.1.

XXXVII. Claims 32-36, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* the CPR1 polypeptide of SEQ ID NO:2 and the B7RP1 polypeptide of SEQ ID NO:7, classified in Class 424, subclasses 143.1.

XXXVIII. Claims 32-36, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* the CPR1 polypeptide of SEQ ID NO:2 and the B7RP1 polypeptide of SEQ ID NO:12, classified in Class 424, subclasses 143.1.

XXXIX. Claims 32-36, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* the CPR1 polypeptide of SEQ ID NO:2 and the B7RP1 polypeptide of SEQ ID NO:17, classified in Class 424, subclasses 143.1.

XL. Claims 32-33 and 35-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of the CPR1 polypeptide of SEQ ID NO:2, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XLI. Claims 32-34 and 36-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of the B7RP1 polypeptide of SEQ ID NO:7, and

further comprising administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XLII. Claims 32-34 and 36-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of the B7RP1 polypeptide of SEQ ID NO:12, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XLIII. Claims 32-34 and 36-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of the B7RP1 polypeptide of SEQ ID NO:17, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XLIV. Claims 32-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* the CPR1 polypeptide of SEQ ID NO:2 and the B7RP1 polypeptide of SEQ ID NO:7, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XLV. Claims 32-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* the CPR1 polypeptide of SEQ ID NO:2 and the B7RP1 polypeptide of SEQ ID NO:12, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XLVI. Claims 32-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* the CPR1 polypeptide of SEQ ID NO:2 and the B7RP1 polypeptide of SEQ ID NO:17, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XLVII. Claims 39 and 42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:7, classified in Class 424, subclass 184.1.

XLVIII. Claims 39-40, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

XLIX. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

L. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering B7.2, classified in Class 424, subclass 193.1..

LI. Claims 39 and 41, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering B7.1 *and* B7.2, classified in Class 424, subclass 193.1.

LII. Claims 39 and 42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:12, classified in Class 424, subclass 184.1.

LIII. Claims 39-40, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering a CD28 agonist, classified in 424, subclass 193.1.

LIV. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

LV. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

LVI. Claims 39 and 41, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering B7.1 *and* B7.2, classified in Class 424, subclass 193.1.

LVII. Claims 39 and 42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:17, classified in Class 424, subclass 184.1.

LVIII. Claims 39-40, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

LIX. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

LX. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering B7.2, classified in Class 424, subclass 193.1..

LXI. Claims 39 and 41, drawn to a method of enhancing an immune response by administering the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering B7.1 *and* B7.2, classified in Class 424, subclass 193.1.

LXII. Claim 39, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:7, classified in Class 514, subclass 885.

LXIII. Claims 39-40, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

LXIV. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

LXV. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

LXVI. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:7 and *further comprising* administering B7.1 and B7.2, classified in Class 424, subclass 193.1.

LXVII. Claim 39, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:12, classified in Class 514, subclass 885.

LXVIII. Claims 39-40, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

LXIX. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

LXX. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

LXXI. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:12 and *further comprising* administering B7.1 *and* B7.2, classified in Class 424, subclass 193.1.

LXXII. Claim 39, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:17, classified in Class 514, subclass 885.

LXXIII. Claims 39-40, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

LXXIV. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

LXXV. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

LXXVI Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the B7RP1 polypeptide of SEQ ID NO:17 and *further comprising* administering B7.1 and B7.2, classified in Class 424, subclass 193.1.

LXXVII. Claims 39 and 42, drawn to a method of enhancing an immune response by administering an *agonist* of the CRP1 polypeptide of SEQ ID NO:2, classified in Class 514, subclass 885.

LXXVIII. Claims 39-40, drawn to a method of enhancing an immune response by administering an *agonist* of the CRP1 polypeptide of SEQ ID NO:2 and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

LXXIX. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering an *agonist* of the CRP1 polypeptide of SEQ ID NO:2 and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

LXXX. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering an *agonist* of the CRP1 polypeptide of SEQ ID NO:2 and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

LXXXI. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of the CRP1 polypeptide of SEQ ID NO:2 and *further comprising* administering B7.1 and B7.2, classified in Class 424, subclass 193.1.

5. Groups I-XII and XXIX-XXII are different products. Nucleic acids, polypeptides, antibodies to the polypeptides and transgenic non-human mammals expressing the polypeptides differ with respect to their structures and physicochemical properties; therefore for these reasons and the reasons set forth supra in Section 3, each product is patentably distinct.

6. Groups (V/XXIX and I), (VI/XXX and II), (VII/XXXI and III) and (VIII/XXXII and IV), respectively, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case the proteins can be made using an amino acid synthesizer.
In the instant case the nucleic acids can also be used to produce the proteins, in addition to use in construction of non-human transgenics.

7. Groups XIII-XXVIII and XXXIII-LXXXI are different methods. As noted supra, these methods utilize distinct products, requiring different method steps. In addition, methods of treating, diagnosing and identifying each differ with respect to ingredients, method steps, and endpoints. Therefore, each method is patentably distinct.

8. Groups (I and XXV), (II and XXVI), (III and XXVII), (IV and XXVIII), (V and XIII/XXI), (VI and XIV/XXII/XLVII-LI), (VII and XV/XXIII/LII-LVI), (VIII and XVI/XXIV/LVII-LXI), (IX and XVII/XXXIII/XXXVII-XXXIX/XL/XLIV-XLVI), (X and XVIII/XXXIV/XXXVII/XLI/XLIV), (XI and XIX/XXXV/XXXVIII/XLII/XLV) and (XII and XX/XXXVI/XXXIX/XLIII/XLVI), respectively, are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the nucleic acids can be used to express the proteins in a prokaryotic expression system, in addition to use in the gene therapy methods recited.
In the instant case, the polypeptides can be used to produce antibodies, in addition to the different methods of modulating an immune response recited.
In the instant case the antibodies can be used for affinity purification, in addition to the methods of treating and diagnosing recited.
Finally, it is note that each method recited is also recited as practicable with another materially different product.

9. Inventions (IX and XXI), (X and XXII), (XI and XXIII), and (XII and XXIV), respectively, are related as products and method of identifying said products. However, the method steps do not define the structure of the claimed products. Therefore, they are patentably distinct

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

11. **If Applicant elects one of Groups XXXIII-XLVI**, Applicant is further required to (1) elect a single disclosed species of each recited "antagonist" or combination thereof (having adequate support in the specification under 35 USC 112, first paragraph), for example, an antibody to the polypeptide of SEQ ID NO:2; to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

12. **If Applicant elects one of Groups LXII-LXXXI**, Applicant is further required to (1) elect a single disclosed species of each recited "agonist" or combination thereof (having adequate support in the specification under 35 USC 112, first paragraph) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

13. This application contains claims directed to the following patentably distinct species of the claimed Inventions XXXIII-XLVI: wherein the IgE-mediated disorder is:

A) asthma, or

B) an allergic disorder.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic.

14. This application contains claims directed to the following patentably distinct species of the claimed Inventions XLVII/XLIX-L/LII/LIV-LV/LVII/LIX-LX/LXXVII/LXXIX-LXXX: wherein the disorder is:

A) cancer, or

B) a viral infection.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 42 is generic.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
February 15, 2002

Phillip Gambel
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2/19/02